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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,098	04/16/2004	Ma. Teresa Y. Tan	DIZ-5	9265

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EXAMINER	
COTTON, ABIGAIL MANDA	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,098	TAN ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/17/06,5/17/06,6/16/06 and 7/24/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/17/06, 5/17/06, 6/16/06 and 7/24/06, have been entered.

Claims 1-16 are pending in the application and are being examined on the merits herein.

The rejection of claims 1-16 under 35 U.S.C. 112, first paragraph, as adding impermissible new matter, is being withdrawn in view of Applicants' amendment to claim 1. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, is also being withdrawn in view of Applicants' amendment to this claim.

Applicant's arguments regarding the rejections of the claims over the prior art have been fully considered but they are not persuasive. In particular, Applicants' have filed a declaration signed by all inventors attempting to show invention of the claimed subject matter prior to the June 6, 2002 publication date of the WO 02/43707 reference

to Khan et al. However, as discussed in more detail below, the Khan et al. reference qualifies as a reference under the provisions of 35 U.S.C. 102(b), and thus cannot be antedated by such a declaration.

Accordingly, the amended claims are rejected as follows.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. In particular, Applicants submission of a certified copy of the foreign priority application PHILIPPINES 12003000285 filed on June 6, 2003, is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 and 15-16 are rejected under 35 U.S.C. 103(a) as being obvious over WO 02/43707 to Khan et al, published June 6, 2002, in view of U.S. Patent No. 6,080,426 to Amey et al, issued June 27, 2000.

Khan et al. teaches an oral pharmaceutical form of cerufoxime axetil where the drug is contained in a tablet core and is coated with a double layered film coat (see abstract, in particular.) Khan et al. teaches that the first film coat masks the bitter taste of the cefuroxime axetil while the second film coat delays the rupture time beyond 40 seconds (see abstract, in particular), and even teaches that the rupture time can be between 45-240 seconds (see page 4, second full paragraph, in particular.) Khan et al. teaches that the delayed rupture time is desirable because patients find it easier to swallow dosage forms that have a longer rupture time (see paragraph bridging pages 3-4, in particular.)

Khan et al. does not specifically teach that the tablet has a rupture time of more than 60 seconds, as recited in claim 1. However, as Khan et al. teaches that the film coat can be selected to provide a rupture time of from 45-240 seconds, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the rupture time, according to the guidance provided by Khan et al, to provide a composition having desired administration properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is

not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 6-8, Khan et al. furthermore teaches that the tablet can contain from 2 to 15% by weight of disintegrant, and that an effective amount of disintegrant can be provided to achieve the desired disintegration of the tablet (preferably within 1 minute) after rupture of the film (see page 5, fourth full paragraph, in particular.)

Regarding claims 9 and 15-16, Khan et al. teaches that the disintegrant can be starch, sodium starch glycolate, croscarmellose sodium and others (see page 5, fourth full paragraph, in particular.) Regarding claim 10, Khan et al. teaches that the cefuroxime axetil is desirably in the amorphous form (see page 1, third full paragraph, in particular.)

Khan et al. does not teach providing the specific % weight ranges of disintegrant in the caplet as recited in claims 6-8. However, Khan et al. teaches providing a range of disintegrant that is overlaps with the range recited in claim 6, and that is very close to the ranges recited in claims 7-8, with the range recited in claim 7 having a lower limit (20%) that is only 5% greater than the preferred upper limit (15%) specified by Khan et al. Khan et al. furthermore teaches of the desirability of providing an effective amount of disintegrant in the tablet to disintegrate the tablet rapidly upon rupture of the film coating. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to optimize the % weight of disintegrant included in the tablet to

provide the desired rate of disintegration of the tablet. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Khan et al. does not specifically teach providing the tablet in a capsule or the composition of the capsule.

Amey et al. teaches that the encapsulation of caplets in a capsule can be performed to provide a dosage form that is more easily swallowable than uncoated caplets (see column 1, lines 15-28, in particular) and that does not exhibit the disadvantageous associated with coated caplet forms, such as non-uniformity of the coating (see column 1, lines 28-50, in particular.) Thus, Amey et al. teaches that encapsulated capsule forms can be provided as an improved alternative to coated or non-coated capsules.

Regarding claims 3-5, Amey et al. teaches a process for encapsulation of caplets in a capsule comprising providing empty capsule parts, filling at least one of said capsule parts with one or more caplets, putting said capsule parts together, and treating the combined parts by cold shrinking (see abstract, in particular.) Amey et al. teaches that a specifically preferred version has a clearance of the capsule shell and caplet in the range of from about 0 to about -0.5 mm, meaning that the caplet is compressed in the capsule (see column 2, lines 50-54, in particular.) Thus, as Amey et al. teaches a

caplet and capsule have less than zero clearance between each other, it follows that the diameter of the caplet taught by Amey et al. must be greater than or equal to 80% of the internal diameter of the capsule taught by Amey et al.

Regarding claims 11-12 and 14, Amey et al. teaches that suitable materials for the capsule can include gelatin, hydroxypropyl methylcellulose or starch (a polysaccharide) (see column 3, lines 18-34, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have been motivated to substitute at least one of the film coats of the greater than 60 second rupture time cerufoxime axetil tablet composition of Khan et al, with a surrounding capsule as taught by Amey et al, because Amey et al. teaches that encapsulation of caplets and tablets can advantageously be performed instead of coating such tablets, and thus teaches the interchangeability of the methods. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to provide the capsule of Amey et al. in place of at least one of the film coats of Khan et al., with the expectation of providing a suitable form for the delayed rupture and release of cerufoxime axetil.

Claims 13-14 are rejected under 35 U.S.C. 103(a) as being obvious over WO 02/43707 to Khan et al, published June 6, 2002, in view of U.S. Patent No. 6,080,426 to Amey et al, issued June 27, 2000, as applied to claims 1-12 and 15-16 above, and

further in view of U.S. Patent No. 6,482,432 to Xiping Wang, issued November 19, 2002.

Khan et al. and Amey et al. are applied as discussed above, and render obvious providing a cefuroxime axetil tablet inside a capsule that ruptures in greater than 60 seconds. Khan et al. and Amey et al. do not specifically teach that the capsule is made of vegetable or plant-based cellulose.

Wang teaches that there is consumer demand for capsules made from vegetable sources, such as vegetable gelatin or hydroxypropyl methylcellulose (see column 1, lines 52-60, in particular.) Wang also provides examples of therapeutic ingredients being encapsulated in cellulose derivative capsules or vegetable cellulose capsules (see column 2, lines 55-61, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have been motivated to provide a capsule made of vegetable based cellulose in the encapsulated caplet dosage form of Khan et al. and Amey et al, with the expectation of providing a capsule that is suitable for encapsulating therapeutic ingredients and that is in demand by consumers.

Response to Arguments

Applicants arguments regarding the rejections of the claims have been fully considered but they are not persuasive.

In particular, Applicants have filed a declaration asserting conception of the invention prior to the June 6, 2002 publication date of the WO 02/43707 reference to Khan, coupled with due diligence from the conception date to the filing of the application with the USPTO (see declaration filed July 24, 2006.) Applicants further argue that the Khan et al. reference does not qualify as prior art under the provisions of 35 U.S.C. 102(e) because Applicants have provided a certified copy of their foreign priority application PHILIPPINES 12003000285 filed June 6, 2003, and thus have established benefit of the foreign priority date. Applicants thus conclude that the submission of the certified copy of the priority application and the antedating declaration are sufficient to remove the Khan et al. publication as a reference.

The Examiner respectfully disagrees with this analysis. In particular, the Examiner notes that the declaration is not effective to overcome the rejections of record because the Khan et al. reference is a statutory bar under 35 U.S.C. 102(b) and thus cannot be overcome by an affidavit or declaration under 37 CFR 1.131. While Applicants have established priority back to the foreign priority filing date of June 6, 2003, this does not change the status of the Khan et al. reference as qualifying under

the provisions of 35 U.S.C. 102(b). In particular, as Applicants have noted, 35 U.S.C. 102(b) stipulates that a person is entitled to a patent unless "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States" (emphasis added.) The filing date of the instant application in the United States is April 16, 2004, which is more than one year after the publication of the Khan et al. reference, and thus the Khan et al. reference qualifies as prior art under the provisions of 35 U.S.C. 102(b). The foreign priority date can be used to overcome intervening references having an effective date that is between the foreign priority and U.S. filing dates, but cannot be used to overcome the 35 U.S.C. 102(b) statutory bar on subject matter published more than one year before filing in the United States, as in the instant case (see MPEP 706.02 section V "Determining the Effective Filing Date of the Application".) Accordingly, Applicants assertion of invention before the effective date of Khan et al. is not effective to remove Khan et al. as a reference, and the claims remain rejected over Khan et a. for the reasons set forth above.

Furthermore, the antedating declaration is unpersuasive because the evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Khan et al. reference to either a constructive reduction to practice or an actual reduction to practice. Establishing diligence requires submission of actual evidence or proof of continued work on an invention, or application claiming such an invention, throughout the entire time period starting just prior to the reference date and

up until reduction to practice or constructive reduction to practice. The mere statement that due diligence "was exhibited" is not sufficient to meet the standard of proof (see MPEP 715.07(a)).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER